MS APPEAL BRIEF - PATENTS
0508-1105

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Filippo BELARDELLI et al. Conf. 1462

Application No. 09/845,042 Group 1644

Filed April 27, 2001 Examiner Gerald R Ewoldt

METHOD FOR GENERATING HIGHLY ACTIVE
HUMAN DENDRITIC CELLS FROM MONOCYTES

Response to Notification of Non-Compliant Brief

Assistant Commissioner for Patents October 25, 2006
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Non-Compliant Brief mailed September 25, 2006, a summary of the claimed subject matter may be found in the present specification as follows:

(v) Summary of the Claimed Subject Matter

The claimed invention is a method for producing dendritic cells from human mononuclear cells. As discussed in the present specification for example at page 1, lines 18-21, dendritic cells are recognized for their antigen-presenting capability, and thus play a key role in priming the immune response. However, as discussed at page 3, lines

18-23 of the specification, the therapeutic use of dendritic cells has been limited by their low occurrence in peripheral blood and the difficulty of harvesting them from bone marrow and lymphoid tissue.

The invention improves upon techniques for producing dendritic cells from human mononuclear cells, e.g. peripheral blood monocytes. That is, previous researchers have shown that it is possible to make dendritic cells by culturing a patient's monocytes *ex vivo* under selected culturing conditions, which results in the transformation ("differentiation") of the cells into a distinct phenotype, namely that of immature dendritic cells (page 3, line 24 - page 4, line 24).

The present inventors have discovered that such dendritic cells can be made more rapidly and in a single step by differentiating the mononuclear cells in the presence granulyte/monocyte colony-stimulating factor (GM-CSF) and type I interferon gamma (IFN), for up to three days (page 5, line 9-14 and line 28-32).

Independent claims 54, 63, 69 and 72 each reflect that discovery, and claim the invention in somewhat different ways, particularly in terms of the amounts of type I IFN and GM-CSF used in the culture.

Claim 54 recites a process for deriving dendritic cells from mononuclear cells in culture wherein the mononuclear cells are peripheral blood mononuclear cells or CD14+ monocytes (page 16, lines 15-25), comprising culturing the mononuclear cells for a maximum of three days (page 9, lines 29 and 32-33) with type I IFN at a concentration of 400 to 10,000 IU/ml in the presence of GM-CSF at a range of 250-1,000 IU/ml (page 5, lines 33-34; page 6, lines 6-15; and page 26, lines 6-8), in the absence of IL-4 (page 26, lines 6-26), and collecting the cells within 3 days of culture (page 9, lines 29 and 32-33).

Claims 63 recites a method for the ex vivo derivation of dendritic cells from mononuclear cells (pg. 5, lines 9-14). While claims 63 and 54 both recite a similar step of culturing mononuclear cells, claim 63 recites different concentration levels of type I IFN and GM-CSF. The recited concentration levels for type I IFN and GM-CSF for all of the claims may be found in the specification at page 5, lines 33-34; page 6, lines 6-15; and page 26, lines 6-8.

Similar to claim 63, claim 69 also recites a method for the ex vivo derivation of dendritic cells from mononuclear cells (pg. 5, lines 9-14). However, claim 69 differs from claim 63 in that different concentration levels

of type I IFN and GM-CSF are used. As noted above, the recited concentration levels for type I IFN and GM-CSF for all of the claims may be found in the specification at page 5, lines 33-34; page 6, lines 6-15; and page 26, lines 6-8.

Claim 72 recites a process similar to claim 54 but further provides that the dendritic cells express higher levels of CD83 and CD25 antigens as compared to mononuclear cells or monocytes that have been cultured within 3 days of treatment with GM-CSF and IL-4 (pg. 19, lines 30-35).

In view of the concise explanation of the claimed subject matter set forth above, it is believed that the requirements of 37 CFR 41.37 (c)(1)(v) are satisfied. As a result, applicants respectfully request favorable consideration of the Appeal Brief filed on September 11, 2006.

Respectfully submitted,

YOUNG & THOMPSON

By Philip DuBois

Philip DuBois
Attorney for Appellant
Registration No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone: 703/521-2297

October 25, 2006